

- 5.1.4 A written procedure which includes all the following elements must be prepared:
- Intended use and criteria for use
 - Assay principle and safety precautions,
 - Acceptable sample types, sample collection method, preparation, preservation, storage and transportation conditions ,
 - Description of reagents supplied or directions for preparation and QC,
 - Description of quality controls to be used
 - Detailed instructions on how to perform the method,
 - Detailed instructions on how to interpret and report the result,
 - Any limitations of the method that are known or suspected,
 - A summary of the performance characteristics of the method,
 - A statement on the target uncertainty of measurements for each analyte (analytical goal for accuracy) in order for the values to be fit for their intended purpose.